## Thermo Fisher

# SOLVED WITH

## patheon

### **Global label services**

The challenge of creating labels for investigational drugs is mounting as more countries sign on to participate in clinical trials. Every investigational study needs labels. Every product. Every comparator. Every visit box. Every shipping box. And unlike any other medicinal product, every clinical label design is unique to every patient.

Recognized as the leading supplier of clinical labeling design, production and management services for the pharmaceutical and biotechnology industries, our Global Label Services team is renowned for providing consistent quality, product accuracy and fast turnaround that is simply unsurpassed in the industry. Our advanced inspection software, full in-house print capabilities, translation and regulatory approval management process, centralized web-based document management/ routing platform, are specifically designed to reduce overall label cycle times.

Our Global Label Services offering, our team leverage purpose-built, integrated facilities, a global presence and the information systems and flexibility to allow unparalleled visibility and control while offering time-saving, seamless transition opportunities throughout the clinical supply chain.

Speed to market	High quality labels	Inspection	Subject matter expertise	Integrated service offering
E	$\checkmark$	***		
<ul> <li>Fast turnaround times</li> <li>Label printing in 4-5 days</li> <li>Expedited label orders by request</li> <li>Inventory of stock</li> <li>Durable, fully laminated labels protect the label data/text from damage at site or in transit</li> </ul>	<ul> <li>Adhering to high quality GLOBAL standards</li> <li>For a range of temperature specifications: <ul> <li>2-8°C</li> <li>Frozen</li> <li>Cryogenic</li> </ul> </li> <li>Different materials and adhesives based on the label application &amp; storage temperature requirements</li> </ul>	<ul> <li>Automatic inspection</li> <li>Optical character recognition (OCR) inspection of variable text</li> <li>Each variable electronically verified against the randomization</li> </ul>	<ul> <li>Specialized, dedicated project managers with expertise in label printing</li> <li>Translation Management</li> <li>Global network of Label Experts on hand to support local team in Suzhou, China</li> </ul>	<ul> <li>Access to a breadth of services <ul> <li>packaging,</li> <li>sourcing, supply chain optimization,</li> <li>storage, distribution,</li> <li>returns and</li> <li>destruction.</li> </ul> </li> <li>Supporting local biotechs on global studies</li> </ul>



#### Fisher Clinical Services<sup>™</sup> Global Label Services Capabilities

- Innovative Product Designs single & two panel; GlobalPly<sup>SM</sup> multi-lingual booklet; DigiPly<sup>SM</sup> digital boolet; ePly<sup>SM</sup> electronic label
- Industry Leading Translation Management Services ATLAS<sup>™</sup>
- Innovative solutions new ePly<sup>SM</sup> electronic label
- · Consultative Project Management
- Adherence to ambient and cold chain specifications (up to -80°C)
- Unique Quality Control Processes

#### **Enabled by**

#### **Dedicated consultative expertise**

Unlike other clinical label providers, label design, translation and support are provided by an extensive team of dedicated consultative project management experts focused solely on clinical trials. Clinical trial label production requires a higher level of oversight and management than a commercial labeling operation in order to protect the integrity of blind, as well as meet stringent regulatory controls.

#### Extensive global reach

By combining our clinical trial project management expertise and expansive global reach, we provide a clinical labeling model that integrates regulatory, packaging and clinical logistics capabilities, to deliver improved timelines and more accurate allocation of clinical trial materials.

#### Expansion of service offering to Asia Pacific region

Our dedicated clinical label in-house print capabilities, combined with an experienced project management team, supports unique clinical label requirements in the Asia Pacific region, adhering to global standards, regulatory requirements and temperature specifications. Our fast and flexible approach delivers on aggressive timelines and clinical trial requirements, reducing packaging & label cycle time and enabling faster access to market.

#### Innovation

The pharma industry is becoming increasingly innovative, with digital platforms and digitalization becoming acceptable business practices in the industry today. Our unique Fisher Clinical Services<sup>SM</sup> ePly<sup>SM</sup> solution is driving the industry towards an optimal solution for an electronic supply chain. ePly<sup>SM</sup> is an innovative end-to-end virtual label solution that utilizes a GMP platform to provide patients, sites and sponsors with digital content that helps to enable patient safety, retention and compliance.

#### Regulatory support

With the pressure on Sponsor companies to accelerate drug development and to access a wider patient pool, the globalization of clinical trials has been notable over the past decade. This results in escalating costs, growing competition, and regulatory controls which require expert guidance and a proactive approach to deliver clinical trials on time. The Global Label Services team incorporates regulatory support and specific label design and configuration to address unique label requirements and temperature specifications.

#### **Translation management**

The Fisher Clinical Services<sup>™</sup> Alternative Translation & Label Approval System (ATLAS<sup>™</sup>) is a Clinical Services proprietary web based tool used for translation management. The industry's first clinical, web-based, label-specific translation and approval management system, comprehensively addresses the full spectrum of label development, streamlining the process from text translation and approval and reducing clinical labeling manufacturing timelines by 50%.

#### Tenure

Backed by years of pharmaceutical and printing industry experience, no company better understands your need for error-free clinical labels delivered on time, every time. This is why, year after year, world-leading pharmaceutical companies, clinical packagers and and Contract Research Organizations (CRO) rely on Thermo Fisher Scientific for a wide range of outsourced products and services.

#### Connect with us

